

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

REC'D 07 NOV 2005

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference DELBE/P32301PC		FOR FURTHER ACTION	See Form PCT/PEA/416
International application No. PCT/GB2004/005435	International filing date (day/month/year) 23.12.2004	Priority date (day/month/year) 23.12.2003	
International Patent Classification (IPC) or national classification and IPC C12N15/81, C12N1/19			
Applicant DELTA BIOTECHNOLOGY LIMITED et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 12.07.2005		Date of completion of this report 07.11.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Cupido, M Telephone No. +31 70 340-3374	



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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-31, 33, 35, 36, 39-41, 44-65, as originally filed
69-72, 78-81, 83-89, 91, 93-98,
101, 102

32, 34, 37-38, 42, 43, 66-68, 73-77, received on 10.02.2005 with letter of 09.02.2005
82, 90, 92, 99-100

Sequence listings part of the description, Pages

1-27 received on 10.02.2005 with letter of 09.02.2005

Claims, Numbers

1-63 as originally filed

Drawings, Sheets

1/79-48/79 as originally filed

49/79-79/79 received on 10.02.2005 with letter of 09.02.2005

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-63
	No: Claims	
Inventive step (IS)	Yes: Claims	1-63
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-63
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in computer readable form
 - ☒ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☒ received by this Authority as an amendment on
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional observations, if necessary:

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: WO 00/44772 A (DELTA BIOTECHNOLOGY LIMITED; VAN URK, HENDRIK; MEAD, DAVID, JOHN; MORT) 3 August 2000
- D2: SLEEP DARRELL ET AL: "Yeast 2 μ m plasmid copy number is elevated by a mutation in the nuclear gene UBC4" YEAST, vol. 18, no. 5, 30 March 2001, pages 403-421, XP008045518 ISSN: 0749-503X
- D3: US-B1-6 291 205 (TUIE MICHAEL F ET AL) 18 September 2001

By defining a site in the 2 μ m-family of plasmid that allows to insert heterologous DNA without creating an unacceptable loss of multicopy stability of the plasmid, the present inventors have overcome the prejudice present in the art for example in D1-D3, that the 2 μ m-family plasmids cannot be suitably used as expression vectors. The subject-matter of the present invention is therefore regarded as novel and to involve an inventive step as required by Article 33 PCT.

Re Item VIII

Certain observations on the international application

The invention concerns yeast expression vectors based on the 2 μ m-family plasmid, wherein the insertion site for the sequence to be expressed is chosen such that the resulting plasmid is still maintained in a stable manner. However, the subject-matter of claims 48 and 55 and claims dependent thereon concerns **any** yeast vector as long as it has a selectable marker allowing the host cell to survive that cannot be complemented by modifications to the culture medium. However, the essential feature that it has to be a

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(SEPARATE SHEET)**

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member of the 2 μ m-family of plasmids and that the marker gene is inserted in the region specified in claim 1 is missing. This is an essential feature of the invention that has to be mentioned in the claims.